

§ 1271.15

(b) If you are a domestic or foreign establishment that manufactures an HCT/P described in paragraph (a) of this section:

- (1) You must register with FDA;
- (2) You must submit to FDA a list of each HCT/P manufactured; and
- (3) You must comply with the other requirements contained in this part.

EFFECTIVE DATE NOTE: At 69 FR 68681, Nov. 24, 2004, §1271.10 was amended by revising paragraph (a)(3), effective May 25, 2005. For the convenience of the user, the revised text is set forth as follows:

§ 1271.10 Are my HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?

(a) * * *

(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

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§ 1271.15 Are there any exceptions from the requirements of this part?

(a) You are not required to comply with the requirements of this part if you are an establishment that uses HCT/P's solely for nonclinical scientific or educational purposes.

(b) You are not required to comply with the requirements of this part if you are an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure.

(c) You are not required to comply with the requirements of this part if you are a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business as a carrier.

(d) You are not required to comply with the requirements of this part if you are an establishment that does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's solely for implantation, transplantation, infusion, or transfer within your facility.

(e) You are not required to comply with the requirements of this part if

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you are an establishment that only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor.

(f) You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.

§ 1271.20 If my HCT/P's do not meet the criteria in § 1271.10, and I do not qualify for any of the exceptions in § 1271.15, what regulations apply?

If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a), and you do not qualify for any of the exceptions in § 1271.15, your HCT/P will be regulated as a drug, device, and/or biological product under the act and/or section 351 of the PHS Act, and applicable regulations in title 21, chapter I. Applicable regulations include, but are not limited to, §§ 207.20(f), 210.1(c), 210.2, 211.1(b), 807.20(d), and 820.1(a) of this chapter, which require you to follow the procedures in subparts B, C, and D of this part.

Subpart B—Procedures for Registration and Listing

§ 1271.21 When do I register, submit an HCT/P list, and submit updates?

(a) You must register and submit a list of every HCT/P that your establishment manufactures within 5 days after beginning operations or within 30 days of the effective date of this regulation, whichever is later.

(b) You must update your establishment registration annually in December, except as required by § 1271.26. You may accomplish your annual registration in conjunction with updating your HCT/P list under paragraph (c) of this section.

(c)(i) If no change described in § 1271.25(c) has occurred since you previously submitted an HCT/P list,

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you are not required to update your listing.

(ii) If a change described in § 1271.25(c) has occurred, you must update your HCT/P listing with the new information:

(a) At the time of the change, or

(b) Each June or December, whichever month occurs first after the change.

§ 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

(i) Establishment registration,

(ii) HCT/P listings, and

(iii) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(i) By writing to the Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator;

(ii) By contacting any Food and Drug Administration district office;

(iii) By calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800;

(iv) By calling the Fax Information System at 1-888-CBER-FAX or 301-827-3844; or

(v) By connecting to <http://forms.psc.gov/forms/FDA/fda.html> on the Internet.

(c)(i) You may submit Form FDA 3356 to the Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator; or

(ii) You may submit Form FDA 3356 electronically in accordance with the instructions provided with the form.

EFFECTIVE DATE NOTE: At 69 FR 68681, Nov. 24, 2004, § 1271.22 was revised, effective May 25, 2005. For the convenience of the user, the revised text is set forth as follows:

§ 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

(1) Establishment registration,

(2) HCT/P listings, and

(3) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(1) By writing to the Center for Biologics Evaluation and Research (HFM-775), Food

and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator;

(2) By contacting any Food and Drug Administration district office;

(3) By calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800; or

(4) By connecting to <http://www.fda.gov/opacom/morechoices/fdaforms/cber.html> on the Internet.

(c)(1) You may submit Form FDA 3356 to the Center for Biologics Evaluation and Research (HFM-775), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator; or

(2) You may submit Form FDA 3356 electronically through a secure web server at <http://www.fda.gov/cber/tissue/tisreg.htm>.

§ 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration Form FDA 3356 must include:

(1) The legal name(s) of the establishment;

(2) Each location, including the street address of the establishment and the postal service zip code;

(3) The name, address, and title of the reporting official; and

(4) A dated signature by the reporting official affirming that all information contained in the establishment registration and HCT/P listing form is true and accurate, to the best of his or her knowledge.

(b) Your HCT/P listing must include all HCT/P's (including the established name and the proprietary name) that you recover, process, store, label, package, distribute, or for which you perform donor screening or testing. You must also state whether each HCT/P meets the criteria set out in § 1271.10.

(c) Your HCT/P listing update must include:

(1) A list of each HCT/P that you have begun recovering, processing, storing, labeling, packaging, distributing, or for which you have begun donor screening or testing, that has not been included in any list previously submitted. You must provide all of the information required by § 1271.25(b) for each new HCT/P.

(2) A list of each HCT/P formerly listed in accordance with § 1271.21(a) for which you have discontinued recovery,